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MAR 14 1996

510(k) Summary
for
Safetech International Inc.'s Doyle Extractor

1. DATE PREPARED

December 14, 1995

2. SPONSOR INFORMATION

Address: Safetech International, Inc.
511 W. Grove Street, Suite 202
Middleboro, MA 02346

Telephone: 508-946-0096

Contact: Patricia A. Doyle

3. DEVICE NAME

Proprietary Name:	Doyle Extractor
Common/Usual Name:	Needle Extractor
Classification Name:	IV Administration Set/Accessory (21 CFR 880.5440, Product Code: 80 FPA)

4. DEVICE DESCRIPTION AND INTENDED USE

The Doyle Extractor is a needle extractor intended for use as an accessory to IV administration sets. Specifically, the Doyle Extractor is intended for use during the removal of right-angle needles from implanted IV ports. It is manufactured from polypropylene and provides a suitable leverage for extraction of right-angle needles from the skin and implanted IV port. The device contains a slot on the top blade to secure the IV tubing prior to removal of the needle.

5. PREDICATE DEVICES

The Doyle Extractor is similar in design, function, and intended use to accessories for other temporary or removable devices. Examples include the AutoSuture skin staple remover (K810187, K914130)--a disposable staple remover which is similar in design, appearance, and function to the Doyle Extractor, as well as the Ethicon skin staple extractor (K760733). Skin staple removers utilize the principle of a simple lever to apply adequate force for removal of the skin staple; the Doyle Extractor utilizes this same principle for removal of the right angle infusion needle from an implanted port. The devices are very similar in design, shape, and size, and even intended use, since all are intended to remove items which are puncturing the skin.

6. DEVICE TESTING

Testing was designed to determine the force required to withdraw a right-angle needle from the skin and injection port, as well as to determine that the material and design characteristics of the device were adequate to meet\provide that required force. Testing results confirmed the suitability of the device material and design for its intended use.